UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/667,848	IKEGUCHI ET AL.
	Examiner	Art Unit	
	RAJIV J. RAJ	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _20 My 2008_.

2a) ☒ This action is **FINAL**.   2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-3,5-20 and 22-24_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1-3,5-20 and 22-24_ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____ .

DETAILED ACTION

Status of Claims

1. This action is in reply to the amendment filed on 20 May 2008.

2. Claims 1-3, 5, 7-9, 11-14, 16, 18, & 22 have been amended.

3. Claims 4 and 21 have been canceled

4. Claims 1-3, 5-20, & 22-24 are currently pending and have been examined.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-3,6-7,9-13, & 15-17 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent, a method/process claim must (1) be tied to another statutory class of invention (such as a particular apparatus) (see at least *Diamond v.* Diehr, 450 U.S. 175, 184 (1981); *Parker v.* Flook, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v.* Benson, 409 U.S. 63, 70 (1972); *Cochrane v.* Deener, 94 U.S. 780, 787-88 (1876)) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing (see at least *Gottschalk v.* Benson, 409 U.S. 63, 71 (1972)). A method/process claim that fails to meet one of the above requirements is not in compliance with the statutory requirements of 35 U.S.C. 101 for patent eligible subject matter. Here claims 1-3,6-7,9-13, & 15-17 fails to meet the above requirements because the limitations are not tied to a statutory class of invention. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. See Benson, 409 U.S. at 71-72. As Comiskey recognized, "the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter." Comiskey, 499 F.3d at 1380 (citing In re Grams, 888 F.2d 835, 839-40 (Fed. Cir. 1989)). Incidental physical limitations, such as data gathering, field of use limitations, and post-solution

activity are not enough to convert an abstract idea into a statutory process. In other words, nominal or token recitations of structure in a method claim do not convert an otherwise ineligible claim into an eligible one.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1.   Determining the scope and contents of the prior art.
    2.   Ascertaining the differences between the prior art and the claims at issue.
    3.   Resolving the level of ordinary skill in the pertinent art.
    4.   Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-3, 5-20, & 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0099302) (hereinafter Bardy) in view of Pence et al. (US 5978751) (hereinafter Pence).

Claim 1

Bardy as shown, discloses the following limitations:

- *accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0008] & [0009])

- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial;* (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)

- *determining whether the result of the statistical analysis exceeds a predetermined threshold value;* (see at least Bardy [0059])

- *accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;* (see at least Bardy [0011], [0035] & [0037])

- *generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;* (see at least Bardy [0033], [0035] Fig.5 Items:26,27,125,129-133 & related text)

Bardy does not disclose the following limitations, however Pence, as shown, does:

- *if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the steps of accessing a trial database, performing and determining while the blinded clinical trial is ongoing.* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50, 52 "Detail 'A'" & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have added this feature into Bardy with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Claim 2

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis;* (see at least Bardy [0048])

- *retrieving only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011])

Claim 3

The combination of Bardy/Pence discloses all the limitations of Claim 1. Pence further discloses the following limitation:

- *the step of waiting for a predetermined time period prior to the repeating step if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value,* (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Claim 5

The combination of Bardy/Pence discloses all the limitations of Claim 1. Pence further discloses the following limitation:

- *the step of storing the grouped database in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure that the integrity of the database is maintained.

Claim 6

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *wherein the step of performing a statistical analysis is executed without locking the trial database* (see at least Bardy [0048])

Claim 7

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *reading a predefined criteria that defines the level of cleanliness of trial data required for analysis*; (see at least Bardy [0048])

- *retrieving only those trial data that meet the predefined criteria from the trial database*; (see at least Bardy [0011])

Claim 8

The combination of Bardy/Pence discloses all the limitations of Claim 7. Bardy further discloses the following limitation:

- *ongoing blinded clinical trial;* (see at least Bardy [0008])

Bardy does not disclose the following limitations, however Pence, as shown, does:

- *wherein the grouped database is stored in a memory device that is inaccessible by any user to preserve the blindness of the clinical trial.* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 9

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *the step of alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.* (see at least Bardy Fig. 5 Item:127 and [0041])

Claim 10

The combination of Bardy/Pence discloses all the limitations of Claim 9. Pence further discloses the following limitation:

- *wherein the predetermined threshold value includes a predetermined statistical significance value* (see at least Pence Column:7 Lines:28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 11

The combination of Bardy/Pence discloses all the limitations of Claim 10. Pence further discloses the following limitation:

- *retrieving a user defined statistical model; and running the retrieved user defined statistical model on the trial database.* (see at least Pence Column:7 Lines:28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 12

Bardy as shown, discloses the following limitations:

- *accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0008] & [0009])
- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial;* (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)

- *accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;* (see at least Bardy [0037])

- *producing a grouped database from the trial database and the blinding database, the grouped database grouping the trial data according to the study group;* (see at least Bardy Fig.5 Items:26,27,125,129-133)

- *determining whether the result of the statistical analysis exceeds a predetermined threshold value;* (see at least Bardy [0059])

Bardy does not disclose the following limitation, however Pence, as shown does:

- *if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the steps of accessing a trial database, performing and determining while the blinded clinical trial is ongoing.* (see at least Pence Fig. 2 Items:50, 52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have added this feature into Bardy with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Claim 13

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis;* and(see at least Bardy [0048])

- *retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis.* (see at least Bardy [0011])

Claim 14

The combination of Bardy/Pence discloses all the limitations of Claim 12. Pence further discloses the following limitations:

- *the step of the produced grouped database in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 15

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *wherein the step of performing a statistical analysis is executed without locking the trial database.* (see at least Bardy [0048])

Claim 16

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *the step of alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.* (see at least Bardy Fig. 5 Item:127 and [0041])

Claim 17

The combination of Bardy/Pence discloses all the limitations of Claim 16. Pence further discloses the following limitations:

- *wherein the predetermined threshold value includes a predetermined statistical significance value.* (see at least Pence Column:7 Lines28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into

Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 18

Bardy as shown, discloses the following limitations:

- *a storage device operable to store a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0035])

- *a processor coupled to the storage device;* (see at least Bardy Fig. 1 Items14,16-18)

- *an analysis program executable by the processor* (see at least Bardy Fig. 5 Items16,131)

- *access the trial database to retrieve the trial data;* (see at least Bardy [0037] & [0043])

- *accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;* (see at least Bardy [0011], [0035] & [0037])

- *generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;* (see at least Bardy [0033], [0035] Fig.5 Items:26,27,125,129-133 & related text)

- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial;* (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)

- *determine whether the output result of the statistical analysis exceeds a predetermined threshold value;* (see at least Bardy [0059])

Bardy does not disclose the following limitation, however Pence, as shown does:

- *repeat the statistical analysis while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50, 52 "Detail 'A'" & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have added this feature into Bardy with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected

data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Claim 19

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitations:

- *read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis;* (see at least Bardy [0048])

- *retrieve only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011])

Claim 20

The combination of Bardy/Pence discloses all the limitations of Claim 18. Pence further discloses the following limitations:

- *wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis.* (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 22

The combination of Bardy/Pence discloses all the limitations of Claim 18. Pence further discloses the following limitation:

- *a memory device coupled to the processor* (see at least Pence Fig. 1 Items:11,15 and related text).

- *being inaccessible to any user, wherein the grouped database is stored only in the memory device.* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 23

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program performs the statistical analysis without locking the trial database* (see at least Bardy [0048])

Claim 24

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value* (see at least Bardy [0059])

Response to Arguments

10. Applicant's arguments received on 20 May 2008 have been fully considered but they are not persuasive. Applicants' arguments will be addressed herein below in the order in which they appear in the response filed 20 May 2008.

    i. Applicant appears to argue that the prior art fails to teach *blinded* trials. However, Examiner notes that this aspect of the limitations fails to make the invention patentable, as this concept is already known in the art. (see at least Applicant's Own Admission [0008])

ii.   Applicant appears to argue that the prior art fails to teach *clinical trials*. However, Examiner

notes that this aspect of the limitations fails to make the invention patentable. While the prior

art may no have an intended use for *clinical trials*, the prior art clearly does disclose the

limitations of the Examiner's application. The teachings of the prior art specifically disclose

the ideas and concepts disclosed in Applicant's limitations.

11. In response to Applicant's remaining arguments, it is respectfully submitted that the Examiner has

applied prior art to amended and original claims 1-3, 5-20, & 22-24. The Examiner notes that the

amended claims were not in the previously pending claims as such, Applicant's additional remarks

with regard to the applications of the prior art used in the first Non-Final Office Actions to the

amended claims are moot in light of the cited prior art references as disclosed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office

action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of

the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from

the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

shortened statutory period, then the shortened statutory period will expire on the date the advisory action

is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX

MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should

be directed to RAJIV J. RAJ whose telephone number is (571)270-3930. The examiner can normally be

reached on Monday thru Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke

Gilligan can be reached on (571)272-6770. The fax phone number for the organization where this

application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application

Information Retrieval (PAIR) system. Status information for published applications may be obtained from

either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC)

at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative

or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-

1000.

/Rajiv J. Raj/, Art Unit 3626
07/28/08

/Robert Morgan/
Primary Examiner, Art Unit 3626